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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|---------------------------|---------------------------------|------------------|
| 10/077,130 | 02/15/2002 | Rosana Kapeller-Libermann | MPI01-047PIRNM | 2926 |
| 7590 06/30/2004 | | | | |
| Jean M. Silveri Millennium Pharmaceuticals, Inc. 75 Sidney Street Cambridge, MA 02139 | | | EXAMINER MONSHIPOURI, MARYAM | |
| | | | ART UNIT 1652 | PAPER NUMBER |

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|---------------------------------------|--|--|
| Office Action Summary | Application No. 10/077,130 | Applicant(s) KAPELLER-LIBERMANN ET AL. | |
| | Examiner Maryam Monshipouri | Art Unit 1652 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-7, 12, 18 drawn to DNA sequences encoding 59079 protein kinase (SEQ ID NO:2), host and vectors comprising said DNA sequences and methods of expressing said DNA sequences, classified in class 435, subclass 194.
- II. Claims 1-7, 12, 18, drawn to DNA sequences encoding 12599 protein kinase (SEQ ID NO:5), kits, hosts and vectors comprising said DNA sequences and methods of expressing said DNA sequences, classified in class 435, subclass 194.
- III. Claims 8-10, drawn to said 59079 protein kinases, classified in class 435, subclass 194.
- IV. Claims 8-10, drawn to said 12599 protein kinases, classified in class 435, subclass 194.
- V. Claims 11-13 and 15, drawn to antibodies which selectively bind said 59079 protein kinase, kits comprising said antibodies, and methods of use of said antibodies, classified in class 435, subclass 7.1.
- VI. Claims 11, 13, and 15, drawn to antibodies which selectively bind said 12599 kinase, kits comprising said antibodies and methods of use of said antibodies, classified in class 435, subclass 7.1.
- VI. Claims 16-17, drawn to methods of detecting DNA sequences encoding said 59079 protein kinase in a hybridization assay, classified in class 435, subclass 6.

- VIII. Claims 16-17, drawn to methods of detecting said 12599 kinase encoding DNA sequences in a hybridization assay, classified in class 435, subclass 6.
- IX. Claims 19-20, 22, drawn to methods of identifying modulators of 59079 protein kinase, classified in class 435, subclass 18.
- X. Claims 19-20 and 22, drawn to methods of identifying ,modulators of said 12599 kinase, classified in class 435, subclass 18.
- XI. Claim 21, drawn to methods of modulating the activity of 59079 kinase, classified in class 435, subclass 18.
- XII. Claim 21, drawn to methods of modulating the activity of 12599 kinas, classified in class 435, subclass 18.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I-VI are patentably distinct each from the other because each invention is directed to products if unrelated chemical structure and function.

The DNA of Group I, the antibodies of Groups V and VI are each unrelated to any of the methods of Group VIII-XII because neither of said products is made or used by any of said methods.

Inventions I and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

process of using that product (MPEP § 806.05(h)). In the instant case the DNA of Group I may be used for recombinant expression of 59079 polypeptide which is a totally different method than that of Group VII.

The DNA of Group II, the antibodies of Groups V and VI are each unrelated to any of the methods of Groups VII, IX, X, XI or XII because neither of said products is made or used in any of said methods.

Inventions II and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the DNA of Group II may be used for recombinant expression of 59079 polypeptide which is a totally different method than that of Group VIII.

Inventions III and IX (or XI) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the kinase of Group II may be used in antibody preparation which is a totally different method than any of those of Groups IX and XI.

The kinase of Group III is unrelated to any of the methods of Groups VII, VIII, X or XII because said products are neither made nor used by any of said methods.

Inventions IV and X (or XII) are related as apparatus and product made. The inventions in this relationship are distinct if either or both of the following can be shown: (1) that the apparatus as claimed is not an obvious apparatus for making the product and the apparatus can be used for making a different product or (2) that the product as claimed can be made by another and materially different apparatus (MPEP § 806.05(g)). In this case the kinase of Group IV may be used in antibody preparation which is a totally different method than any of those of Groups X and XII.

The kinase of Group IV is unrelated to any of the methods of Groups VII, VIII, IX or XI because said products are neither made nor used by any of said methods.

The methods of Groups VII-XII are each patentably distinct from the other because each method has different steps and different end-points.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provision of MPEP section 821.04. **Process claims that depend from or**

otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all the criteria for patentability including the requirement of 35 U.S.C. 101, 102, 103 and 112. Until an asserted product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. section 103(b)," 1184 O.G. 86(March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include limitations of the product claim. **Failure to do so may result in a loss of the right to rejoinder.**

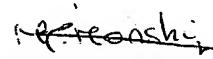
Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP section 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maryam Monshipouri whose telephone number is (571) 272-0932. The examiner can normally be reached on 7:00 a.m to 4:30 p.m. except for alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnanthapu Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Maryam Monshipouri Ph.D.

Primary Examiner
